510(k): K120912

PREMARKET NOTIFICATION 510(k) SUMMARY

JUN 15 2012

The submitter of the 510(k) is

Martin A. Kaufman
Director, Regulatory Affairs
Alcon Research Ltd.
18500 Alton Parkway
Irvine, CA 92618
Phone: (949) 753-6250
Fax: (949) 753-6237

Device Subject to the 510(k)

Trade Name:	INFINITI® Vision System
Common Name:	Phacofragmentation System
Classification Name:	Phacofragmentation System per 21 CFR 886.4670

Predicate Devices:

The legally marketed devices(s) to which we are claiming equivalence to are:

510(k) number	Device
K112425	INFINITI® Vision System (Evergreen II)
K093210	AquaLase Capsule Wash Tip
K091777	Alcon UltraChopper Tip
K082845	INFINITI® Vision System with OZil® IP
K063155	Monarch III Delivery System (includes C & D cartridges)
K021566	INFINITI® Vision System

Device Description

The INFINITI® Vision System is unchanged from the INFINITI® Vision System (Evergreen II - K112425) and maintains the modular design and incorporated features that include: Power Watch feature, UltraChopper tip, the AquaLase Capsule Wash Tip, the INTREPID® AutoSert™ IOL Injector Handpiece, and the system's associated software.

Indications for use:

The INFINITI® Vision System is indicated for emulsification, separation, and removal of cataracts, the removal of residual cortical material and lens epithelial cells, vitreous aspiration and cutting associated with anterior vitrectomy, bipolar coagulation, and intra-ocular lens injection. The INTREPID® AutoSert® IOL Injector Handpiece is intended to deliver qualified AcrySof® intraocular lenses into the eye following cataract removal.

The following system modalities additionally support the described indications:

- Ultrasound with UltraChopper Tip achieves the functionality of cataract separation.
- AquaLase achieves the functionality for removal of residual cortical material and lens epithelial cells.
- The INTREPID® AutoSert® IOL Injector Handpiece achieves the functionality of injection of intraocular lenses. The INTREPID® AutoSert® IOL Injector Handpiece is indicated for use with AcrySof® lenses SN60WF, SN6AD1, and SN6AT3 through SN6AT9, as well as approved AcrySof® lenses that are specifically indicated for use with this inserter, as indicated in the approved labeling of those lenses.

Brief Summary of Nonclinical Tests and Results:

Safety tests of the INFINITI® Vision System have been demonstrated its compliance with all applicable requirements that were covered in K112425. Additional testing that covers the additional AcrySof® intraocular lenses SN6AT3 through SN6AT9 was completed per EN ISO 11979-3, Section 5. Each AcrySof® lens was tested with the Monarch® II C Cartridge and the Monarch® III D Cartridge. This submission makes no changes whatsoever to the INFINITI® Vision System console, Sterilization parameters, Biocompatibility of materials, System Software, or the Electromagnetic and Electrical Safety.

Standard #	Title
EN ISO 11979-3: 2006	Ophthalmic implants - Intraocular lenses-Part 3: Mechanical Properties and Test Methods, Section 5.

Accessories

Many INFINITI® accessories are provided sterile and are intended for single use only. These products are EtO sterilized and the process has been validated per AAMI/ISO 11135-1:2007: Medical Devices – Validation and routine control of Ethylene Oxide Sterilization. Reusable Handpieces are provided non-sterile. Validated reprocessing instruction for cleaning, sterilization, and re-use of the Handpieces are provided in the Directions for Use provided with the product.

Conclusions

Technological characteristics affecting the clinical performance are unchanged to that of the predicate devices previously listed. The INFINITI® Vision System has been developed and will be manufactured in compliance with 21CFR 820 and ISO 14971:2007. Non-clinical testing noted above has demonstrated that functional requirements have been met and that this device is equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Alcon Research, Ltd.
c/o Mr. Martin Kaufman, RAC
Director, Regulatory Affairs
15800 Alton Parkway
Irvine, CA 92816

JUN 15 2012

Re: K120912
Trade/Device Name: Infiniti Vision System
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation system
Regulatory Class: II
Product Codes: HQC, HQR, MLZ, KYB
Dated: March 21, 2012
Received: March 26, 2012

Dear Mr. Kaufman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jessica Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known) K120912
Device Name: INFINITI® Vision System

Indications for Use:

The INFINITI® Vision System is indicated for emulsification, separation, and removal of cataracts, the removal of residual cortical material and lens epithelial cells, vitreous aspiration and cutting associated with anterior vitrectomy, bipolar coagulation, and intra-ocular lens injection. The INTREPID® AutoSert® IOL Injector Handpiece is intended to deliver qualified AcrySof® intraocular lenses into the eye following cataract removal.

The following system modalities additionally support the described indications:

- Ultrasound with UltraChopper Tip achieves the functionality of cataract separation.
- AquaLase achieves the functionality for removal of residual cortical material and lens epithelial cells
- The INTREPID® AutoSert® IOL Injector Handpiece achieves the functionality of injection of intraocular lenses. The INTREPID® AutoSert® IOL Injector Handpiece is indicated for use with ACRYSOF lenses SN60WF, SN6AD1, SN6AT3 through SN6AT9, as well as approved AcrySof® lenses that are specifically indicated for use with this inserter, as indicated in the approved labeling of those lenses.

Prescription use ___X___ AND/OR Over-The-Counter _____
(Pat 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K120912